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Panel Unanimously Recommends Cervical Cancer Vaccine for Girls 11 and Up

By GARDINER HARRIS

A federal vaccine advisory panel voted unanimously yesterday to recommend that all girls and women ages 11 to 26 receive a new vaccine that prevents most cases of cervical cancer.

The vote all but commits the federal government to spend as much as \$2 billion alone on a program to buy the vaccine for the nation's poorest girls from 11 to 18.

The vaccine, Gardasil, protects against cancer and genital warts by preventing infection from four strains of the <a href="https://www.numen.new.n

Gardasil is manufactured by Merck and should be available within days. Girls as young as 9 can receive the vaccine if doctors wish, the panel voted.

But Gardasil's benefits could be blunted by a complex brew of practical, economic and religious considerations. On the practical side, Gardasil is supposed to be given as three shots over six months. While pediatricians and government health agencies have long been successful in having parents adhere to complex <u>vaccination</u> schedules for infants, older children are more difficult to manage.

Another challenge is Gardasil's price. At \$360 for the three-shot regimen, it is among the most expensive vaccines ever. Because cervical cancer is mostly a disease of poverty, those in most need of the vaccine will be the least able to afford it. State vaccination programs, already under financial strain, may refuse to provide it.

"This vaccine will be more expensive than all other childhood vaccines put together," said John Schiller, a senior investigator at the <u>National Cancer Institute</u>, whose

discoveries underpinned Gardasil's development. "How do you make sure it gets to the poor women who need it the most?"

Because Gardasil prevents a sexually transmitted disease, some religious groups have sounded reservations about vaccinating young girls.

"You can't catch the virus, you have to go out and get it with sexual behavior," said Linda Klepacki of Focus on the Family, a conservative Christian group based in Colorado Springs. "We can prevent it by having the best public health method, and that's not having sex before marriage."

Ms. Klepacki's group opposes mandating Gardasil vaccinations. States and school districts have the power to decide whether to mandate vaccinations, but such decisions are usually not made until at least a year after a vaccine is introduced.

In a news conference, the federal panel, the Advisory Committee on Immunization Practices, Dr. Anne Schuchat, director of the immunization program at the <u>Centers for Disease Control and Prevention</u>, called the panel's approval of Gardasil historic and "a breakthrough for women's health."

Though the vaccine is costly, studies presented at the meeting showed that its widespread use would save more in health expenses than the cost of buying the vaccine. In the United States, 9,710 women contract cervical cancer each year, and 3,700 die. Millions of women have annual Pap smears to test for cervical cancer, and tens of thousands undergo further expensive testing and procedures after receiving false positive tests.

Such testing will continue in part because the vaccine's preventive effects are years away but also because Gardasil does not protect against viral strains that cause up to 30 percent of cervical cancers.

Cervical cancer is far more deadly in the developing world. Worldwide, it affects 470,000 women and kills 233,000 each year. Merck and some international health groups have said they are committed to making Gardasil available in the developing world, but the World Health Organization is already struggling to provide a worldwide \$3.50 vaccine against five major killer diseases.

In the United States, health insurers will probably cover the cost of vaccinations, Dr. Schuchat said. Poor girls without insurance should be able to get the vaccine through Vaccines for Children, a federal program that distributes nearly half of all vaccines.

In fact, the panel's vote all but commits the federal government to buy vaccines for as many as seven million girls at a total price that could exceed \$2 billion. The <u>Department of Health and Human Services</u> must confirm this decision, but such affirmations are routine.

After the government initiates a "catch-up" campaign focusing on girls from 13 to 18, it will seek to vaccinate all 11- and 12-year-olds routinely. The vaccine is most effective if given before girls first have sex.

Girls who are not poor enough to qualify for the federal program but who do not have adequate private insurance may have difficulty obtaining Gardasil. Most states have programs to vaccinate those who fall between the health system's cracks, but budgets are already strained.

Merck also hopes someday to receive approval to have boys vaccinated with Gardasil, which protects against two strains of virus that cause 90 percent of genital warts.

Although a few religious groups have expressed mild reservations about the vaccine, many conservative organizations support it.